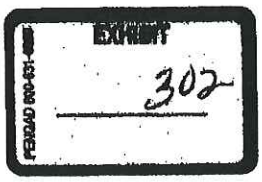
Brigham and Womens Hospital
Department of Pharmacy
USP <797> Audit of NECC
May 14, 2012



Company Audited: New England Compounding

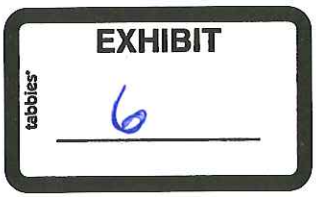
Site Audited: 50 Fountain Street
Framingham, MA 01702

Brigham and Womens Auditors: *Lead:* Francis McAteer
Microbiology Research Associates, Inc.

Michael Cotugno, Rph
Pharmacy Manager

NECC Participants: *Lead:* Barry Caden, Rph

Focus of Inspection: To assess the acceptability of New England Compounding as a USP <797> Compliant Sterile Compounding Facility for Brigham and Womens Hospital Department of Pharmacy.



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EXECUTIVE SUMMARY

New England Compounding (NECC) is a contract sterile compounding facility located in Framingham, MA. It is registered with the FDA and holds Controlled substances Registrations with the State of Massachusetts and the U.S. DEA. The organization currently has approximately 25-30 full-time employees. A report is enclosed.

Overall, NECC is compliant for USP_{34} <797> regulations and is therefore acceptable for the performance of sterile compounding preparations as contracted by Brigham and Womens Hospital Department of Pharmacy.

AUDIT REFERENCES

United States Pharmacopeia (USP) 34th edition, Section <797> Sterile Compounding.

AUDIT AGENDA

The audit covered:

- Facility Design and Environmental Controls Review
- Compounding Procedures
  - Processing
  - Component Acceptance
  - Verification of Accuracy and Sterility
  - Finished Lot Release Testing
- Environmental Quality and Control Procedures
- Standard Operating Procedures
- Environmental Monitoring
  - Sampling Plan
  - Air/Surface/Personnel Monitoring
  - Particle Counts and Pressure Differential
- Technician Training and Qualifications
  - Personnel Cleansing and Garbing
  - Media Proficiency
- Storage/Packing/Transport
  - Label/NDC Bar Code Quality Control
- Cleaning/Sanitization Records
- Equipment Calibration/Validation/Maintenance File
- Quality Assurance Program
  - Follow-up/Corrective Action and Preventative Action (CAPA) Program

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GENERAL

NECC was very cooperative and open in supplying documentation. BWH reviewed the following customer complaints, cleaning/disinfection logs, current NECC SOPs.

- Operational Training Files
- Environmental Monitoring Reports
- Equipment Calibration Recents
- Warehousing Procedures
- Storage and Transport
- Alarm and Security Systems

All documentation seemed adequate and compliant to GMP.

A facility walk through was informative and demonstrated an overall quality compliance.

RECOMMENDATIONS

1. **Establish USP <797> Action Limits for Viable Air Sampling.**

   NECC has an establish environmental monitoring standard operating procedure (SOP). The SOP details viable monitoring by surface and air. Action limits are in place. However, the action limits for viable air are >2cfu/m^3 which are not aligned with current USP <797> action levels of >1cfu/m^3.

2. **Assess the quality levels of Applied Research Labs (ARL) for GMP and 797 Compliance.**

   ARL is a 3rd party contract chemistry and microbiology lab for NECC CSPs. No quality assessment for GMP on USP <797> has been performed. This is a critical CSP release laboratory and should be audited for compliance to appropriate USP compendial compliance.

3. **There is no internal deviation reporting.**

   Internal deviation reporting from established NECC procedures should be established. This should include documentation, investigation and corrective action for any deviation or out of specification results. Presently, there is no system in place.

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CONCLUSION

No response from NECC is required. NECC has been approved for sterile compounding preparations for Brigham and Womens Hospital Department of Pharmacy.

Fran McAteer
Microbiology Research Associates, Inc.

Date

Michael Cotugno
Brigham and Womens Hospital

05/30/12
Date